REMARKS

I. INTRODUCTION

Claims 1, 4, 5, 8, 13, 16, 17, 20, 25, 28-30, 32, 37 and 38 have been amended as provided above merely to remove minor informalities therefrom and to address the Examiner's comments. Claims 43-46 have been added. Claims 9-11, 21-23, 33-35 and 40-42 have previously been withdrawn. Accordingly, claims 1-46 of the above-identified application are currently pending and claims 1-8, 12-20, 24-32, 36-39 and 43-46 are currently under consideration. Provided above, please find a claim listing indicating the current amendments on separate sheets so as to comply with the requirements set forth in 37 C.F.R. § 1.121. It is respectfully asserted that no new matter has been added. Support for the subject matter in the amendments to claims 1, 5, 8, 13, 17, 20, 25, 29, 30, 32, 37 and 38, and the addition of new claims 43-46 can be found in the originally-filed specification, drawings and claims of the above-identified application.

II. OBJECTION TO OATH/DECLARATION SHOULD BE WITHDRAWN

The Examiner asserts that the declaration filed on May 16, 2006 is allegedly defective because all of the copies of the declaration do not list each inventor. (*See* Office Action, p. 2).

MPEP 201.03 II B and MPEP 605.04(a), relied upon by the Examiner in asserting this objection (see, Office Action, p. 2), both state that "[a]n oath or declaration under 37 CFR 1.63 by each actual inventor must be presented [and w]hile each inventor

need not execute the same oath or declaration, each oath or declaration executed by an inventor must contain a complete listing of all inventors so as to clearly indicate what each inventor believes to be the appropriate inventive entity." (MPEP 201.03 II B and MPEP 605.04(a)).

Applicants respectfully assert that the declaration executed by all three inventors, Gilad Lerman, Joseph McQuown and Bud Mishra on May 12, 2006, May 12, 2006 and May 15, 2006, respectively, were so executed with each inventor having seen all pages of the declaration containing a complete listing of all inventors so as to clearly indicate what each inventor believes to be the appropriate inventive entity, in full compliance with MPEP 201.03 II B and MPEP 605.04(a). Enclosed herewith, please find the separate declarations as were executed by the inventors.

Therefore, Applicants respectfully assert that this objection to the declaration should be withdrawn.

III. REJECTION UNDER 35 U.S.C. § 101 SHOULD BE WITHDRAWN

The Examiner has rejected claims 1-8, 12-20, 24-32 and 36-39 under 35 U.S.C. § 101 as allegedly being directed to non-statutory subject matter. (*See* Office Action, p. 3).

A. Claims 1-8 and 12

With respect to amended independent claim 1 and claims 2-8 and 12 which depend therefrom, the Examiner contends that a physical transformation of matter allegedly is not provided, and that "[a]s such, the claims *must* be further

evaluated for providing the practical application." (*Id.*, pp. 3-4, *emphasis added.*) The Examiner further asserts that "[o]ne way to do this is for the claim to produce a concrete, tangible and useful result." (*Id.*, p. 4, *emphasis added*) The Examiner alleges that the result of the claimed invention is purportedly not tangible and that there is allegedly no "real-world" practical application of the statistically outlying data points; and, therefore that the instant set of method claims allegedly lack a practical application. (*Id.*) The Examiner further believes that in addition to providing a practical application, "the claim **must also meet** the machine-or-transformation test" (*Id., emphasis in the original.*)

In view of the recent Federal Circuit decision of *In re Bilski*, the test employed by the Examiner for 35 U.S.C. § 101 is improper. Indeed, with respect to the method claims, the *In re Bilski* decision provides the currently-applied test. Specifically, the *In re Bilski* opinion states "that the 'useful, concrete and tangible result' inquiry is inadequate" and reaffirms that "the machine-or-transformation test outlined by the Supreme Court is the proper test to apply." (*In re Bilski*, p. 20). "To the extent that some . . . decisions relied on considerations or tests, such as 'useful, concrete and tangible result,' that are no longer valid as explained above, those aspects of the decisions should no longer be relied on." (*Id.*, p. 23). "Thus, we reexamine the facts of certain cases under the correct test to glean greater guidance as to how to perform the § 101 analysis using the machine-or-transformation test." (*Id.*, pp. 23-24). "The machine-or-transformation test is a two-branched inquiry; an applicant may show that a process claim satisfies § 101 either by showing that his claim is tied to a particular machine, or by showing that his claim transforms an article." (*Id.*, p. 24).

Amended independent claim 1 recites, *inter alia*, "with a processing arrangement and using an adaptively selected multiscale strip function, identifying the statistically-outlying data points present in the at least one dataset based on information contained in the at least one dataset." Applicants respectfully assert that amended independent claim 1, as well as claims 2-8 and 12 which depend therefrom, certainly recite statutory subject matter, *e.g.*, tied to a particular machine (e.g., a processing arrangement). Again, amended independent claim 1 explicitly recites with the processing arrangement in the identifying procedure, thereby **tying the method to a particular machine** and satisfying the machine-or-transformation test of *In re Bilski*.

Thus, the rejection of amended independent claim 1, and claims 2-8 and 12 which depend therefrom, under 35 U.S.C. § 101 as allegedly being directed to non-statutory subject matter should be withdrawn.

In addition, new claim 43, which depends from independent claim 1, recites the display of the statistically-outlying data points and/or storage thereof in a statutory user-accessible format and/or user-readable format, thereby **involving a physical transformation** of data in a machine, thereby also satisfying the machine-or-transformation test of *In re Bilski*.

Moreover, Applicants respectfully assert that claim 1 and the claims which depend therefrom certainly provide a useful, concrete and tangible result, and clearly a practical application. Contrary to the Examiner's assertion on p. 4 of the Office Action that there allegedly is no "real world" practical application of the statistically-outlying data points, Applicants respectfully point out that amended independent claim 1 itself

recites an exemplary embodiment including receiving at least one dataset and, with a processing arrangement and using an adaptively selected multiscale strip function, identifying the statistically-outlying data points present in the at least one dataset based on information contained in the at least one dataset.

Thus, clearly, one having ordinary skill in the art at the time the above-identified application was filed, would certainly have known what the output containing the statistically-outlying data points represents. Further, one having ordinary skill in the art at the time the above-identified application was filed would have clearly understood that a useful, concrete and tangible result is generated based on the recitation of the claim itself, *e.g.*, in view of the specification which provides additional exemplary embodiments of how exemplary results can be used. (See, *e.g.*, Specification, paras. [0051] - [0065].) Therefore, even under the alleged proper test employed by the Examiner, the rejection of claim 1, and claims 2-8 and 12 which depend therefrom, under 35 U.S.C. § 101 as allegedly being directed to non-statutory subject matter, which test is improper in view of the prevalent case law, should be withdrawn.

B. Claims 13-20, 24-32, 34 and 37-39

Amended independent claim 13 recites a software arrangement operable by a processing arrangement for identifying the statistically-outlying data points present in at least one dataset based on the information contained in the at least one dataset, the software arrangement that includes instructions for executing the recited procedures amended as provided in independent claim 1. Amended independent claim 25 recites a storage medium which includes thereon a software arrangement to be executed by a

processing arrangement for identifying the statistically-outlying data points present in the at least one dataset based on information contained in the at least one dataset, the software arrangement including instructions for performing the recited procedures as provided in amended independent claim 1. Amended independent claim 37 recites a system comprising a processing arrangement operably configured to perform the recited procedures as provided in amended independent claim 1. Thus, Applicants respectfully assert that the rejection of claims 13-20, 24-32, 34 and 37-39 under 35 U.S.C. § 101 for the same reasons of allegedly not having a useful, concrete and tangible result should also be withdrawn for at least the following reasons.

As discussed above, the *In re Bilski* reaffirms that the <u>machine-or-transformation test</u> outlined by the Supreme Court is the proper test to apply and that, to the extent that some decisions relied on other considerations or tests that are no longer valid, those aspects of the decisions should no longer be relied on. As amended independent claims 13, 25 and 37 at least recite and are **tied to a particular machine** (e.g., a processing arrangement) independent amended independent claims 13, 25 and 37 clearly satisfy the **<u>machine-or-transformation test</u>** of *In re Bilski*. In addition, claim 25 also recites a storage medium, and claim 37 also recites a system which are additionally machines as set forth in the *In re Bilski* decision. Again, as the court in *In re Bilski* made clear, other tests, such as "useful, concrete and tangible result" test relied upon by the Examiner, should no longer be relied on. Thus, the rejection of amended independent claims 13, 25 and 37, and the claims which depend therefrom, respectively, under 35 U.S.C. § 101 as allegedly being directed to non-statutory subject matter should be withdrawn.

Therefore, for at least the reasons cited above, the rejection of claims 1-8, 12-20, 24-32 and 36-39 under 35 U.S.C. § 101 as allegedly being directed to non-statutory subject matter should be withdrawn.

IV. REJECTIONS UNDER 35 U.S.C. § 112 SHOULD BE WITHDRAWN

The Examiner has rejected claims 1-8, 12-20, 24-32 and 36-39 under 35 U.S.C. § 112, second paragraph as allegedly being indefinite (*See* Office Action, p. 5).

A. Claims 1, 13, 25 and 37

With respect to amended independent claims 1, 13, 25 and 37, the Examiner contends that there is insufficient antecedent basis for the recitation of "the information" in these claims. As the Examiner shall ascertain, independent claims 1, 13, 25 and 37 have been amended to recite "information" instead of "the information". Thus, the rejection of amended independent claims 1, 13, 25 and 37 under 35 U.S.C. § 112 is now moot, and should therefore be withdrawn.

B. Claims 4, 16 and 28

With respect to amended claims 4, 16 and 28, the Examiner contends that these claims are indefinite because it is allegedly indefinite as to the means of shifting a matrix which represents data values, by a mass. For example, as discussed in paragraph [0020] of the specification, "each row of [the matrix] is shifted by a center of mass of the set." Applicants respectfully assert that it would have been clear to one having ordinary skill in the art at the time the above-identified application was filed that each row of the matrix is shifted by a center of mass of the set, which may vary from set to set. Thus, the rejection of amended claims 4, 16 and 28 under 35 U.S.C. § 112 should also be withdrawn.

C. Claim 37

With respect to amended independent claim 37, the Examiner contends that this claim is indefinite because of the phrasing of the steps with respect to the recitation of "receiving" and "identifying" and suggests changing such to "receive" and "identify" accordingly. As the Examiner shall ascertain, independent claim 37 has been amended to recite "receive" and "identify" instead of "receiving" and "identifying" as suggested by the Examiner. Thus, the rejection of amended independent claim 37 under 35 U.S.C. § 112 is now met, and should therefore be withdrawn as well.

D. Claims 5, 8, 17, 20, 29 and 32

With respect to claims 5, 8, 17, 20, 29 and 32, the Examiner contends that it is not clear from each claim in light of the specification as to what quantities the plurality of mathematical symbols represent, and recommends that for clarity, Applicants define the variables and constants within the claims. As the Examiner shall ascertain, claims 5, 8, 17, 20, 29 and 32 have been amended to define the variables and constants within the claims to address the Examiner's concerns and expedite the prosecution of the above-identified application, and not for any reason related to the patentability thereof. Thus, the rejection of amended claims 5, 8, 17, 20, 29 and 32 under 35 U.S.C. § 112 should also be withdrawn.

In summary, for at least the reasons cited above, the rejection of claims 1-8, 12-20, 24-32 and 36-39 under 35 U.S.C. § 112, second paragraph should be withdrawn.

V.   REJECTIONS UNDER 35 U.S.C. § 102(b) SHOULD BE WITHDRAWN

Claims 1, 4, 5, 37 and 38 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Pearson, Philosophical Magazine, vol. 2, 1901 pp. 559-572 (the "Pearson Publication"). Claims 1-3 and 37-39 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Mutch et al., BMC Bioinfomatics, vol. 3, June 2002 (the "Mutch Publication"). Claims 1, 4, 5, 13, 16, 17, 25, 28, 29 and 37 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 6,221,592 issued to Schwartz et al. (the "Schwartz Patent").

First, Applicants respectfully assert that the Pearson Publication does not disclose the subject matter recited in amended independent claims 1 and 37, and claims 4 and 5, and 38 which depend from amended independent claims 1 and 37, respectfully, for at least the following reasons. Second, Applicants respectfully assert that the Mutch Publication does not disclose the subject matter recited in amended independent claims 1 and 37, and claims 2 and 3, and claims 38 and 39 which depend from amended independent claims 1 and 37, respectfully, for at least the following reasons. Third, Applicants further respectfully assert that the Schwartz Patent does not disclose the subject matter recited in amended independent claims 1, 13, 25 and 37, and claims 4 and 5, claims 16 and 17, and claims 28 and 29 which depend from independent claims 1, 13 and 25, respectfully, for at least the following reasons. Accordingly, it is respectfully requested that the rejections under 35 U.S.C. § 102(b) be withdrawn.

In order for a claim to be rejected as anticipated under 35 U.S.C. § 102(b), each and every element as set forth in the claim must be found, either expressly or inherently described, in a single prior art reference. Manual of Patent Examining Procedure §2131; *also see Lindeman Machinenfabrik v. Am Hoist and Derrick*, 730 F.2d 1452, 1458 (Fed. Cir. 1984).

A. Rejection #1 over the Pearson Publication Should be Withdrawn

The Pearson Publication relates to representing a system of points in a plane, three or higher dimensioned space by the "best-fitting" straight line or plane. (See, *e.g.*, Pearson Publication, p. 559).

Amended independent claim 1 recites, *inter alia*,

> A process for identifying statistically-outlying data points in at least one dataset, comprising:
>
> a) receiving the at least one dataset; and
>
> b) with a processing arrangement and using an adaptively selected multiscale strip function, identifying the statistically-outlying data points present in the at least one dataset based on information contained in the at least one dataset

Amended independent claim 37 recites, *inter alia*, a system comprising:

> a processing arrangement operably configured to:
>
> a) receive the at least one dataset; and
>
> b) using an adaptively selected multiscale strip function, identify the statistically-outlying data points present in the at least one dataset based on information contained in the at least one dataset

Thus, amended independent claims 1 and 37 of the above-identified application both recite, *inter alia,* the use of an adaptively selected multiscale strip function.

Applicants respectfully assert that the Pearson Publication fails to disclose, **using an adaptively selected multiscale strip function** the identification of the statistically-outlying data points present in the at least one dataset based on information contained in the at least one dataset, as explicitly recited in amended independent claims 1 and 37 of the above-identified application.

In the Office Action, the Examiner contends that the figure on page 566 of the Pearson Publication allegedly illustrates the acquisition of a datastep and the use of an ellipse to statistically distinguish outlying data points within the dataset in two dimensional space. (*See* Office Action, pp. 7 and 8).

However, as provided on page 559 of the Pearson Publication, for example, the Pearson Publication describes determining the allegedly "best-fitting" _straight line_ or _plane_ to represent a system of points. (See, *e.g.*, Pearson Publication, p. 559, *emphasis added*). The Pearson Publication uses a <u>linear regression</u> to perform such function. In contrast, the adaptively selected multi-strip function recited in amended independent claims 1 and 37 can be non-linear. In particular, the Pearson Publication does <u>not</u> disclose at all the use of <u>an adaptively selected strip function</u>, much less an **adaptively selected *multiscale* strip function**, as explicitly recited in amended independent claims 1 and 37 of the above-identified application.

Therefore, for at least the reasons cited above, the rejection of amended independent claims 1 and 37, and claims 4-5 and 38 which depend from amended independent claims 1 and 37 respectively, under 35 U.S.C. § 102(b) as allegedly being anticipated by the Pearson Publication should be withdrawn.

B. Rejection #2 over the Mutch Publication Should be Withdrawn

The Mutch Publication relates to a "gene selection model . . . based on the observation that: (1) variance of gene expression is [purportedly] a function of absolute expression; (2) one [allegedly] can model this relationship in order to set an appropriate lower fold change limit of significance; and (3) this relationship [purportedly] defines a function that can be used to select differentially expressed genes." (Mutch Publication, Abstract). "The model first evaluates fold change (FC) across the entire range of absolute expression levels for any number of experimental conditions." (*Id.*) "Genes are systematically binned, and those genes within the top X% of highest FCs for each bin are evaluated both with and without the use of replicates." (*Id.*). "A function is fitted through the top X% of each bin, thereby defining a limit fold change." (*Id.*). "All genes selected by the 5% FC model lie above measurement variability using a within standard deviation (SDwithin) confidence level of 99.9%." (*Id.*)

Applicants respectfully assert that the Mutch Publication also fails to disclose **using an adaptively selected multiscale strip function**, to identify the statistically-outlying data points present in the at least one dataset based on information contained in the at least one dataset, as explicitly recited in amended independent claims 1 and 37 of the above-identified application.

In the Office Action, the Examiner specifically contends that the paragraph bridging pages 2 and 3 of the Mutch Publication allegedly discloses the comparison of gene expression in organs of mice. (*See* Office Action, p. 9). However, the paragraph bridging pages 2 and 3 of the Mutch Publication merely states that the model presented

therein "was developed with a data set from a nutritional experiment in a mouse model . . . where the effects of four diets were compared in a number of organs (pool of five mice for each sample in each organ): (1) control diet A in duplicate from the same pool; (2) diet B; (3) diet C; and (4) diet D." (Mutch Publication, p. 2). The Mutch Publication's disclosure "take[s] only the data from the liver as an example for the development of a gene selection model." (Id., pp. 2 and 3). "The model was [allegedly] validated by real-time polymerase chain reaction (RT-PCR) and [allegedly] indicates good concordance between the two experimental techniques." (Id., p. 3). Applicants respectfully assert that the paragraph bridging pages 2 and 3 of the Mutch Publication relied upon by the Examiner does not disclose "using an adaptively selected multiscale strip function, identify[ing] the statistically-outlying data points present in the at least one dataset based on information contained in the at least one dataset" as explicitly recited in amended independent claims 1 and 37 of the above-identified application.

The Examiner also relies on Figure 1b on page 4 of the Mutch Publication as allegedly "illustrat[ing] selection of data under the two conditions of the top 1% and 10% highest fold changes of data and separates out the lower fold changes of gene expression as outliers." (See Office Action, p. 9). Further, the Examiner asserts that the "paragraph bridging columns 1 and 2 of page 8 of [the Mutch Publication allegedly] describes the instrumentation used to scan arrays to convert signals to data." Applicants respectfully disagree.

First, according to the Mutch Publication, data is separated into equal-sized bins, which may create variable sized strip-widths. However, the strip-widths of

the Mutch Publication are <u>neither multiscale nor adaptively selected</u>. As discussed in the Mutch Publication on page 9, left column, paragraph 2, "[i]n each bin the (1-X)-percentile fold change corresponding to a fold change that is exceeded by X% of genes in the bin is determined [and f]or X% between 1% and 10%, m = 200 appears to be suitable." (Mutch Publication, p. 9, left col., para. 2).

Second, the function used in the Mutch Publication for determining a threshold is ad hoc, and obtained by a least squares fit to a model given by an equation of the form a+b/Z. As discussed in the Mutch Publication on page 9, left column, paragraph 4, "[a] continuous model is derived from the discrete one by relating the mean expressions of each bin with the corresponding (1-X)-limit fold change, <u>using a least squares fit</u> of the equation: (1-X)-LFC = a + b/Z (minimum expression)[, which] equation appears to fit the data very well and, the interpretation of the parameters (a and b) is straightforward." (*Id.*, para. 4).

In contrast, according to the above identified application, a smoothed function can be obtained by averaging over many multiscale adaptively selected strip functions, which is abbreviated as "multi-strip functions" as recited in amended independent claims 1 and 37 of the above-identified application. Clearly, the use of a least squares fit model, as described in the Mutch Publication, in no way discloses the use of the adaptively selected multi-strip functions, as recited in amended independent claims 1 and 37 of the above-identified application.

Therefore, for at least the reasons cited above, the rejection of amended independent claims 1 and 37, and claims 2-3 and 38-39 which depend from amended

independent claims 1 and 37 respectively, under 35 U.S.C. § 102(b) as allegedly being anticipated by the Mutch Publication should be withdrawn.

C. Rejection #3 over the Schwartz Patent Should be Withdrawn

The Schwartz Patent "relates to single molecule optical sequencing methods and systems for determining the nucleotide sequence of individual double stranded nucleic acid molecules elongated and fixed to a solid-surface by nicking the nucleic acid molecule, enzymatically adding labeled nucleotides and imaging the labeled nucleotides." (Schwartz Patent, Abstract).

Amended independent claim 13 recites, *inter alia,*

> A software arrangement operable by a processing arrangement for identifying the statistically-outlying data points present in at least one dataset based on the information contained in the at least one dataset, the software arrangement comprising:
>
> a) a first set of instructions operable to configure the processing arrangement to receive the at least one dataset; and
>
> b) using an adaptively selected multiscale strip function, a second set of instructions operable to configure the processing arrangement to identify the statistically-outlying data points present in the at least one dataset based on information contained in the at least one dataset.

Amended independent claim 25 recites, *inter alia,*

> A storage medium which includes thereon a software arrangement to be executed by a processing arrangement for identifying the statistically-outlying data points present in the at least one dataset based on the information contained in the at least one dataset, the software arrangement comprising:
>
> a) a first set of instructions operable to configure the processing arrangement to receive the at least one dataset; and
>
> b) using an adaptively selected multiscale strip function, a second set of instructions operable to configure the processing

26

arrangement to identify the statistically-outlying data points present in the at least one dataset based on information contained in the at least one dataset.

Thus, amended independent claims 1, 13, 25 and 37 of the above-identified application all recite the use of, *inter alia,* "an adaptively selected multiscale strip function."

Applicants respectfully assert that the Schwartz Patent fails to disclose at least **using an adaptively selected multiscale strip function** to identify the statistically-outlying data points present in the at least one dataset based on information contained in the at least one dataset, as explicitly recited in amended independent claims 1, 13, 25 and 37 of the above-identified application.

In the Office Action, the Examiner contends that "Figure 11 of [the Schwartz Patent allegedly] illustrates the computerized limitations of the instant set of rejected claims." (Office Action, p. 10). The Examiner further asserts that "Figure 9 of [the Schwartz Patent], as described in column 9, lines 27-28, is a variable block diagonal matrix for the dynamic programming [and that c]olumn 52, lines 15-43 of [the Schwartz Patent allegedly] describe[s] that for data points that lie within the 'dark' region of Figure 9, a conventional Gaussian function is applicable; for 'white' regions that are outlying the blackened region, the special functions in Equation 8 in column 52 of [the Schwartz Patent] need to be applied." (*Id.*)

However, Applicants respectfully assert that the Schwartz Patent does not disclose at all identifying the statistically-outlying data points using a **multiscale strip function**, much less **using an adaptively selected multiscale strip function,** as

explicitly recited in amended independent claims 1, 13, 25 and 37 of the above-identified application.

Therefore, for at least the reasons cited above, the rejection of amended independent claims 1, 13, 25 and 37, and the claims which depend therefrom respectively, under 35 U.S.C. § 102(b) as allegedly being anticipated by the Schwartz Patent should be withdrawn.

VI. REJECTIONS UNDER 35 U.S.C. § 103(a) SHOULD BE WITHDRAWN

Claims 6-8, 12, 18-20, 24, 30-32 and 34 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the Schwartz Patent in view of Journal of Computational Chemistry, vol. 17, 1996, pp 1229-1244 (the "Beroza Publication").

Applicants respectfully assert that the Schwartz Patent and the Beroza Publication, taken alone or in combination, do not teach or suggest the subject matter recited in claims 6-8, 12, 18-20, 24, 30-32 and 34 for at least the following reasons. Accordingly, it is respectfully requested that the 35 U.S.C. § 103(a) rejection of these claims be withdrawn for at least the reasons set forth herein below.

"To reject claims in an application under Section 103, an examiner must show an unrebutted *prima facie* case of obviousness." *In re Rouffet*, 47 U.S.P.Q.2d 1453, 1455 (Fed. Cir. 1998). The Supreme Court in *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966), stated:

> Under Section 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in

the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined.

Indeed, to sustain a rejection under 35 U.S.C. § 103(a), there must be some teaching, other than the instant application, to alter the prior art to arrive at the claimed invention. "The problem confronted by the inventor must be considered in determining whether it would have been obvious to combine the references in order to solve the problem." *Diversitech Corp. v. Century Steps, Inc.*, 850 F.2d 675, 679 (Fed. Cir. 1998).

The objective standard for determining obviousness under 35 U.S.C. § 103, as set forth in *Graham v. John Deere, Co.*, 383 U.S. 1 (1966), requires a factual determination to ascertain: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; and (3) the differences between the claimed subject matter and the prior art. Based on these factual inquiries, it must then be determined, as a matter of law, whether or not the claimed subject matter as a whole would have been obvious to one of ordinary skill in the art at the time the alleged invention was made. *Graham*, 383 U.S. at 17. Courts have held that there must be some suggestion, motivation or teaching of the desirability of making the combination claimed by the applicant (the "TSM test"). *See In re Beattie*, 974 F.2d 1309, 1311-12 (Fed. Cir. 1992). This suggestion or motivation may be derived from the prior art itself, including references or disclosures that are known to be of special interest or importance in the field, or from the nature of the problem to be solved. *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996).

Although the Supreme Court criticized the Federal Circuit's application of the TSM test, *see KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741, (2007) the Court also indicated that the TSM test is not inconsistent with the *Graham* analysis recited in the *Graham v. John Deere* decision. *Id.*; *see In re Translogic Technology, Inc.*, No. 2006-1192, 2007 U.S. App. LEXIS 23969, *21 (October 12, 2007). Further, the Court underscored that "it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *KSR*, 127 S. Ct. at 1741. Under the precedent established in *KSR*, however, the presence or absence of a teaching, suggestion, or motivation to make the claimed invention is merely one factor that may be weighed during the obviousness determination. *Id.* Accordingly, the TSM test should be applied from the perspective of a person of ordinary skill in the art and not the patentee, but that person is creative and not an automaton, constrained by a rigid framework. *Id.* at 1742. However, "the reference[s] must be viewed without the benefit of hindsight afforded to the disclosure." *In re Paulsen*, 30 F.3d 1475, 1482 (Fed. Cir. 1994).

The prior art cited in an obviousness determination should create a reasonable expectation, but not an absolute prediction, of success in producing the claimed invention. *In re O'Farrell*, 853 F.2d. 894, 903-04 (Fed. Cir. 1988). Both the suggestion and the expectation of success must be in the prior art, not in applicant's disclosure. *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1207 (Fed. Cir. 1991) (citing *In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988)). Further, the implicit and inherent teachings of a prior art reference may be considered under a Section 103 analysis. *See In re Napier*, 55 F.3d 610, 613 (Fed. Cir. 1995).

Secondary considerations such as commercial success, long-felt but unsolved needs, failure of others, and unexpected results, if present, can also be considered. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-39 (Fed. Cir. 1983). Although these factors can be considered, they do not control the obviousness conclusion. *Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 768 (Fed. Cir. 1988).

To establish obviousness, the prior art references must be evaluated as a whole for what they fairly teach and neither the references' general nor specific teachings may be ignored. *Application of Lundsford*, 357 F.2d. 385, 389-90 (CCPA 1966). A reference must be considered for all that it teaches, not just what purportedly points toward the invention but also that which teaches away from the invention. *Ashland Oil, Inc. v. Delta Resins & Refractories*, 776 F.2d. 281, 296 (Fed. Cir. 1985).

It is admitted in the Office Action that the Schwartz Patent "does not teach computing stopping points using a top-down procedure ultimately used to define boundaries between data and outlying data", then, the Examiner relies on the Beroza Publication as allegedly teaching such subject matter. (*See* Office Action, p. 11).

The Beroza Publication relates to "use [of] continuum electrostatic theory to calculate pK_as of amino acids in protein." (Beroza Publication, Abstract). "A Green's function formalism, based on a finite-difference solution to the Poisson-Boltzmann equation for a unit point charge, yields electrostatic potentials that allow calculation of amino acid pK_as to an estimated accuracy of tenths of a pK_a unit." (*Id.*) "Using this method, . . . a sensitivity analysis of calculated pK_as in the photosynthetic reaction center [was performed]." (*Id.*) "Calculated pK_as are most sensitive for residues that are not well-exposed to solvent." (*Id.*) "Variations in the parameters of the continuum

electrostatic model cause pK_a shifts that are larger than the accuracy of the numerical method, but probably not large enough to account for some of the discrepancies between calculated and experimentally measured pK_as that have been reported." (*Id.*)

Claims 6, 18 and 30 each recite, *inter alia*, that "the strip functions that define boundaries that identify the statistically-outlying data points present in the at least one dataset are generated by computing a stopping point F_Q using a top-down procedure." Applicants respectfully assert that at least such subject matter is not disclosed by the alleged combinations of the Schwartz Patent and the Beroza Publication.

As discussed above with respect to the rejections under 35 U.S.C. § 102(b), the Schwartz Patent fails to disclose the subject matter recited in amended independent claims 1, 13 and 25 of the above-identified application, from which claims 6-8 and 12, claims 18-20 and 24, and claims 30-32 and 34 depend from, respectively. The Beroza Publication does not cure the deficiencies with respect to amended independent claims 1, 13 and 25, nor does the Examiner contend that it does. Thus, for at least these reasons, the rejection of claims 6-8, 12, 18-20, 24, 30-32 and 34 under 35 U.S.C. § 103(a) should be withdrawn.

VII. **NEW CLAIMS**

New claims 43-46, which depend from amended independent claims 1, 13, 25 and 37, respectively, have been added above to recite certain subject matter which Applicant believes includes novel features and is separately patentable. Support for this new claim can be found in the originally-filed specification, drawing and claims.

In particular, new claims 43-46 recite, *inter alia*, "at least one of display[ing] or stor[ing] the statistically-outlying data points in a storage arrangement in at least one of a user-accessible format or a user-readable format." For at least the reasons discussed above with respect to amended independent claims 1, 13, 25 and 37, Applicant respectfully asserts that neither the Pearson Publication, the Mutch Publication, the Schwartz Patent nor the Beroza Publication, taken alone or in combination, disclose, teach or suggest the subject matter recited in new claims 43-46 of the above-identified application.

VIII.   <u>CONCLUSION</u>

In light of the foregoing, Applicants respectfully submit that all claims under consideration 1-8, 12-20, 24-32, 36-39 and 43-46 and thus all pending claims 1-46 are in condition for allowance. Prompt consideration, reconsideration and allowance of all of the claims of the above-identified application are therefore earnestly solicited. If any issues remain outstanding, the Examiner is invited to contact the undersigned via the telephone number provided below.

Respectfully submitted,

Date: August 31, 2009

By: _____
Randall M. Berman
Patent Office Reg. No. 61,609

DORSEY & WHITNEY, L.L.P.
250 Park Avenue
New York, New York 10177

Attorney(s) for Applicant(s)
(212) 415-9371